K081673

IONICS
MEDICAL CORPORATION

M. Laine Mashburn
President and Chief Executive Officer

NOV 14 2008

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June 09, 2008

510(K) SUMMARY

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title of the Code of Federal Regulations 21 CFR 807.87(h) and in particular 21 CFR 807.92, the following summary of safety and effectiveness information is provided:

A. Submitted by

M. Laine Mashburn
Company President and Director of Regulatory Affairs
Ionics Medical Corporation
248 Bird Haven Lane
P.O. Box 179
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Telephone: (910) 428-9726
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B. Device Name

Trade or Proprietary Name: Dyn-ALIF Anterolateral Intervertebral Body Fusion Device
Common or Usual Name: Spinal Implant or Intervertebral Body Fusion Device
Classification Name: Intervertebral Body Fusion DeviceWith Bone Graft, Lumbar Fixation Orthosis
Device Class: Class II
Classification: 21 CFR 888.3080
Product Code: MAX

C. Predicate Devices

The subject device is substantially equivalent to the NuVasive CoRoent System intervertebral body fusion device, K071795; the Surgical Dynamics Ray TFC intervertebral body fusion device, P950019/S9; the Ionics Levante Intervertebral Pillar vertebral body replacement device, K983667 and the Medtronic Sofamor Danek Verte-Span Spinal System vertebral body replacement device, K010930 and K024049.

D. Device Description

The Dyn-ALIF Anterolateral Intervertebral Body Fusion Device is an implantable device manufactured from titanium alloy which is available in the abutting plate interface

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dimension of 20mm x 30mm and a vertically expandable height ranging from 11mm anterior /9mm posterior to 15mm anterior/13mm posterior to suit the individual anatomic conditions of the patient. The assembled device consists of five components: two abutting plates with hollow threaded shafts, a central turnbuckle sleeve and two locking set screws. The components can be rigidly locked into a variety of heights, with each construct height measured for the individual case

E. Intended Use

The Dyn-ALIF device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device is designed for use with autogenous bone graft to facilitate fusion at either one level or two contiguous levels in the lumbar spine from L2 to S1 for the treatment of degenerative disc disease (DDD) with up to grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had at least six months of non-operative treatment. The device is intended to be used with supplemental internal spinal fixation systems which are cleared by the FDA for use in the lumbar spine.

F. Substantial Equivalence

Data was provided which demonstrate the Dyn-ALIF Anterolateral Intervertebral Body Fusion Device to be substantially equivalent to previously cleared devices. The substantial equivalence is based upon equivalence in indications for use, design, function, material, labeling, biocompatibility, performance and standards with the named intervertebral body fusion predicate devices and upon equivalence in design (vertical expansion), material and labeling with the named vertebral body replacement predicate devices.

G. Summary of Non-Clinical Tests

Mechanical testing data was presented.

H. Summary of Clinical Tests

(Not Applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 14 2008

Ionic Medical Corporation
% M. Laine Mashburn
President and Chief Executive Officer
248 Bird Haven Lane
Ether, North Carolina 27247

Re: K081673
Trade/Device Name: Dyn-ALIF Anterolateral Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Names: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: October 29, 2008
Received: November 3, 2008

Dear M. Laine Mashburn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081673

Device Name: Dyn-ALIF Anterolateral Intervertebral Body Fusion Device

Indications for Use:

The Dyn-ALIF device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device is designed for use with autogenous bone graft to facilitate fusion.

The Dyn-ALIF device is intended for use at either one level or two contiguous levels in the lumbar spine from L2 to S1 for the treatment of degenerative disc disease (DDD) with up to grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used in patients who have had at least six months of non-operative treatment. The device is intended to be used with supplemental internal spinal fixation systems which are cleared by the FDA for use in the lumbar spine.

Prescription Use ___XX___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081673